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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|----------------------|
| 09/852,455 | 05/09/2001 | Arthur J. Blume | 2598-4004US1 | 5124 |
| 7590 | 03/23/2004 | | EXAMINER | |
| MORGAN & FINNEGAN, L.L.P. 345 Park Avenue New York, NY 10154-0053 | | | | WESSENDORF, TERESA D |
| | | ART UNIT | PAPER NUMBER | |
| | | 1639 | | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/852,455 | BLUME ET AL. | |
| | Examiner | Art Unit | |
| | T. D. Wessendorf | 1639 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 October 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-55 is/are pending in the application.

4a) Of the above claim(s) 2,3,11,13,14 and 17-55 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 4-12 and 15-16 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Status of Claims

Claims 1-55 are pending in the application.

Claims 2-3, 11 (with respect to the non-elected receptors, transcription and translation regulatory sites), 13-14 and 17-55 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12.

Claims 1, 4-12 and 15-16 are under examination.

Specification

The objection to the disclosure with respect to the use of hyperlinks and incomplete U.S. Patent No. has been overcome with the amendment to the specification.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-12, 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons advanced in the last Office action.

Response to Arguments

Applicants argue that the term "precursor", as one skilled in the art would reasonably understand that the applicant had possession of the claimed subject matter. Applicants argue that a non-limiting example of a precursor is clearly given on page 5, lines 18-19, as "polypeptides which may be modified posttranslationally." Applicants argue that it is well known in the art that post-translational modification of polypeptides is sometimes required to convert immature polypeptides into the active, mature form of a protein. Said post-translational modifications can include acetylation of side chains. Applicants argue that prosinsulin is an example that is modified post-translationally into insulin by enzymatic cleavage of the precursor after spontaneous folding of the immature polypeptide.

In response, the definition of the term is not at issue. As applicants admit said term has been defined in the art. But the definition provided in the specification of a "polypeptide which may be modified post-translationally" is in itself too general of a definition. As applicants recognized above, there are too numerous, general ways by which said modifications can be made. Furthermore, the statement as to the different post-translational modifications, are simply arguments, not supported in the as-filed specification. As argued, the modifications **include** only some of those recited above. This does not preclude other modifications such as substitutions, deletions, additions of the post-translationally modified peptide, singly or in combinations with the above.

Applicants' arguments with respect to the precursor, proinsulin is unclear. The as-filed specification does not disclose said specific precursor, proinsulin. And, as apparent from the above arguments, there are numerous factors that can affect the conversion of a precursor to its final form.

Applicants urge that the functional language of a "precursor" combined with the structural example of polypeptides is sufficient to meet the written description requirement. That

no further definition is necessary, since a patent need not teach and preferably omits what is well known in the art.

In reply, as stated by applicants the specific structure of a polypeptide has to be known for a proper cleavage of the precursor of an enzyme. Thus, if applicants choose to rely upon general knowledge in the art to render his disclosure complete, then applicants must show that anyone skilled in the art would have actually possessed the knowledge, *In re Lange* (CCPA 1981) 644 F2d 856, 209 USPQ 288, or would reasonably be expected to check the source which applicants rely upon to complete his disclosure and would be able to locate the information with no more than reasonable intelligence. There is no explicit description in the specification as to the method of identifying a precursor. Applicants can rely upon prior art which would enable one skilled in the art to glean therefrom the necessary information to render the specification complete with respect to the first paragraph of 35 USC 112. But the burden is on applicants to point out precisely where such disclosure lies. However, not everything which may be cited as prior art to preclude the grant of a patent can be equated with common knowledge for the purposes of meeting the written description requirement of 112.

Applicants argue that step (b) of claim 1 can be found for example, at page 21, lines 26 up to page 23, line 17.

In response, applicants appear not to appreciate the rejection. The rejection is based on the broad definition of a precursor. It is not controverted that the written description is drawn specifically to the naturally occurring binding partner, but not to its precursor.

Accordingly, the specific written description for the naturally occurring binding partner would not be adequate for the (incompletely) disclosed precursor. See University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-12, 14-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Response to Arguments

A. Applicants arguments as to the method of identifying the motifs by the argued steps are noted. However, step (a) would appear less confusing, if the method steps were claimed, in the order, as argued.

Applicants argue that gene product of the naturally occurring binding partner and protein encompasses any post translation modifications as clearly stated at page 5, lines 30-31 of the specification.

In response, the definition appears at odds with the claim. It appears from the claim that the gene product being "...the naturally occurring binding partner or partner precursor" and not just the precursor.

B. Applicants argue that according to MPEP 211.03, it is not necessary that the consisting essentially of language meet the 35 USC 112, second paragraph statute but only in overcoming the prior art. However, MPEP also states that said language should be read in the light of the specification. In the context of the claimed randomized amino acid sequences, "consisting essentially of about" is unclear or not positively recited in the as-filed specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 102(a) as being anticipated by Blume et al (Biopolymers, 2000) for reasons as set forth in the last Office action.

Response to Arguments

Applicants argue that Blume is not prior art as the date of publication, 2000, is incorrect due to clerical error in the 1149. Applicants urge that according to the publisher, the date of availability to the public through online publication was 2/1/2001. The reference was dispatched to the public on 2/6/01. Therefore, applicants urge that the reference is not available as prior art due to the priority date of 5/9/00 of the instant application based on the provisional application.

In reply, the publication date, not taken from the 1449, but from the journal itself, Biopolymer (Peptide Science), vol.

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55, 347-356 (2000) clearly shows the publication date and can be indexed as of 2000. Accordingly, this is a proper prior art.

Claims 1, 4-5, 9-12 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kraft (The Journal of Biological Chemistry, 1/22/1999) for reasons advanced in the last Office action.

Response to Arguments

Applicants admit that Kraft reports examples of human proteins containing the DLXXL motif in Table II, where the motif is shown to compete with fibronectin binding to integrin. But argues that Kraft states that the possible biological relevance of such homologies remain unknown and further that 'we have no indication were, if at all, the xxDLxxlx sequences play a biological role with integrin". Applicants urge that based on these statements, it is clear Kraft were not using phage display coupled with amino acid sequence comparisons to find naturally occurring binding partners.

In reply, applicants are taking the Kraft statement out of context. Kraft states "...FASTA search of the GEMBL databases revealed several-extracellular matrix components related consensus sequences...including fibrinogen...With the exception of tenascin, which has been reported to bind in an RGD-dependent way to...av β 6, none of these molecules has been implicated

previously as a ligand for $\alpha\beta\beta_6$, thus, the possible biological relevance of such homologies remains unknown...". Even so, applicants' arguments are not commensurate in scope with the claims. None of the claims recite for any biological relevance of the obtained naturally occurring binding partner, let alone its precursor.

Applicants' further arguments that the sequence peptides disclosed by Kraft do not resemble the natural partners are nothing more than conclusory statements without any evidentiary support.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-12 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft in view of Kay et al (6,303,574) for reasons of record.

Response to Arguments

The arguments above under Kraft are applied herein as applicants did the same. It is argued that Kay does not mention any homology to known binding partners. The references are not properly combined as they are directed to non-analogous art. Kay is argued, to disclose SH3 binding peptides.

In reply, Kay is not employed for the purpose as argued. Rather, for its teachings that the length of the random peptide can be varied. Even without Kay, Kraft's disclosure of a peptide of 6-12 residues approximates the claimed of **about** 20 amino acids. About is a warning that exactitude is not claimed but rather a contemplated variation. About is entitled to latitude in characterizing feature which was not critical to distinction over prior art. General Foods v. Perk Foods Co., 157 USPQ 14.

Contrary to applicants' assertion, these two references belong to analogous art. SH3 and the DXL are both peptides that deal or are concern with carcinoma.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this

action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claims 2-3, 11, 13-14 and 17-55 drawn to a non-elected invention with traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0812. The fax phone numbers for the organization where this application or proceeding is assigned

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are (703) 308-7924 for regular communications and (703) 308-7924
for After Final communications.

Any inquiry of a general nature or relating to the status
of this application or proceeding should be directed to the
receptionist whose telephone number is (703) 308-0196.

T. D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw

March 20, 2004